STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition to Connecticut Senate Bill 188

March 1, 2022

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully opposes proposed Senate Bill 188 because it seeks to require a manufacturer of branded medicines to provide its products to another drug or biologic manufacturer in a manner which is duplicative of, and in conflict with, recently enacted federal law in this space.

This legislation seeks to inject the state into a dynamic between innovator manufacturers and generic and biosimilar product developers to address a concern that has already been addressed by a federal law enacted in 2019. Indeed, this legislation in Connecticut predates the federal law and is seeking to solve an issue that Congress has now addressed. As such, state activity in this space is unnecessary and likely to raise preemption concerns.

Under the federal law commonly referred to the CREATES Act, which was signed into law on December 20, 2019, upon request of an eligible product developer ("developer") that complies with the provisions of CREATES, an innovator must provide sufficient quantities of covered product to the developer for development and testing within a specified timeframe on "commercially reasonable, market based terms," which shall mean a price that does not exceed the product's most recent wholesale acquisition cost. If an innovator fails to do so, then a developer can sue the innovator in federal court to seek injunctive relief, attorney's fees, and a monetary award.

SB 188 attempts to advance the same policy objective that is already addressed by the CREATES Act: ensuring provision of samples to developers by innovators. Enacting SB 188 is therefore unnecessary.

In addition to being duplicative of federal law, SB 188 would be inconsistent with federal law, disrupting the federal objective underlying CREATES and raising preemption concerns. For example, the CREATES Act contemplates that a developer will receive an FDA authorization letter, referred to as a "covered product authorization," to obtain samples of a product subject to a REMS with ETASU ("elements to assure safe use") before it could bring suit against the innovator. SB 188 contemplates no such process or other safety protections but instead contains a confusing cross reference to inapplicable federal law.

In addition to the federal legislation passed by Congress and signed into law, FDA has taken steps to address the process for obtaining samples for generic/biosimilar drug development, including to implement the CREATES Act. These actions by FDA further obviate any need for SB 188.

First, before the CREATES Act was even enacted, FDA established a process for generic applicants to request, from FDA, a letter stating that the potential generic applicant seeking samples of a drug subject to a REMS with ETASU has safety protections in its study protocol that are comparable to those in the REMS. The draft guidance document is intended to "facilitate[] prospective generic applicants' access to . . .supplies to conduct

the testing necessary to support [generic] approval."[1] Second, to facilitate implementation of the CREATES Act, FDA has published information about how to request a covered product authorization and indicated that guidance will be published.[2]

Because of the existing robust statutory and regulatory federal framework, state action in this space is unnecessary and likely to be preempted, so PhRMA respectfully urges opposition to SB 188.

*****

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested more than $1 trillion in the search for new treatments and cures, including $91.1 billion in 2020 alone.

[1] https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm425662.pdf
[2] https://www.fda.gov/drugs/guidance-compliance-regulatory-information/access-product-samples-creates-act